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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,721	09/22/2003	Sek Chuen Chow	GJE-73D1	9693

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SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
2421 N.W. 41ST STREET
SUITE A-1
GAINESVILLE, FL 326066669

EXAMINER

WARE, DEBORAH K

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/667,721

Applicant(s)

CHOW ET AL.

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claims 1-6 are presented for examination on the merits.

Miscellaneous Papers

The Preliminary amendment of September 22, 2003, has been received and the instant case is a continuation of serial no. 09/889,252 filed August 27, 2001, now abandoned. The amendment to the specification is noted, however, Applicant should also update the status of the parent case noted above at page 1, line 1 of the specification.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on October 27, 2003, was received. The submission is in compliance with the provisions of 37 CFR 1.97.

Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are rendered vague and indefinite for the phrase "capable of inducing apoptosis in reactive T-cells" wherein it is unclear in the claims as to whether the characteristics of the excretory-secretory product are adequately defined by such

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language. It is unclear whether this is a required activity of the product or what? The metes and bounds of the claims can not be determined. It is suggested to clarify the claims by requiring the claims to positively recite that the excretory-secretory product induces apoptosis in reactive T-cells. Further, the term "substantially pure" in claim 6 renders the claim indefinite because the intended meaning of the term "substantially" is not well defined in the specification as to how it should be read in the claim. What does "substantially pure" mean as defined by the specification? Deletion of the term and insertion of --biologically-- is suggested. Also the term "isolatable" used in the claims does not clarify that the product is positively isolated from *Necator americanus* and a positive recitation such as --biologically purified-- is suggested.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371⁹ of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined

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under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 4-6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over newly cited WO 95/12615.

1. Claims are drawn to compositions comprising a carrier or a pharmaceutically acceptable diluent, and an excretory-secretory product, isolatable from *Necator americanus*. The compositions capable of inducing apoptosis in reactive T-cells. Also a method for treating inflammation is claimed.

WO 95/12615 teaches compositions comprising a carrier or a pharmaceutically acceptable diluent, and an excretory-secretory product, isolatable from *Necator*

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americanus See the abstract and page 2, lines 5-8. Treating thrombosis is disclosed.

Note page 1, lines 1-10.

The claims are identical to the newly cited disclosure and thus, are considered to be anticipated by the teachings therein. The capability of inducing apoptosis in reactive T-cells is an inherent property of the product. However, in the alternative that the products are different as claimed due to some unidentified claimed characteristic which is not taught by the cited reference then the claims are rendered alternatively prima facie obvious over the cited reference. In the alternative that there is some difference then one of ordinary skill in the art would have been motivated to provide for the compositions with the expectation of successful results for inducing apoptosis in reactive T-cells since the products are derived from hook worms and these are well known in the art to be useful for treating thrombosis and hence inflammation as thrombosis is well known in the art to induce inflammation of tissues. When cells are inhibited they can die off and as a result inflammation is decreased. The claims are at least prima facie obvious.

Claims 1 and 4-6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over new cited Brophy et al..

Claims are discussed above. Brophy teaches excretory-secretory products isolatable from *Necator americanus*. Note page 1, lines 1-10 and the abstract. Also note page 260, lines 1-10 of first full paragraph of which continues to page 261. Also note page 262, last paragraph, all lines. Brophy clearly teach that the products can be used to treat inflammations.

Claims are identical to the teachings of the cited Brophy reference and thus are anticipated by the reference. The capability of the compositions to induce apoptosis in T-cells is an inherent property of the composition. However, in the alternative that there is some characteristic which has not been clearly identified in the claims for which to make the reference differ somewhat from the claims then this difference is considered to be so slight as to render the claims prima facie obvious. The property of apoptosis is an inherent property of the composition as there is no difference in how the compositions are prepared. The disclosed method of preparation of the disclosed compositions is so similar to the claimed compositions, thus, the compositions are the same and would have the same properties, or alternatively would have been expected to provide for the same properties. Thus, the claims are at least prima facie obvious.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over newly cited Vlasuk et al.

2. In addition to as discussed above, the claims are also drawn to a method for treating cancer.

3. Vlasuk et al. teach a composition comprising the excretory-secretory product isolatable from *Necator americanus* and further teach that such compositions can be administered for treating infections and cancer. Note column 37-38 all lines and column 3, 65-66.

The claims are identical to the cited disclosure and are therefore, considered to be anticipated by the teachings of Vlasuk. However, in the alternative that there is some unidentified claimed characteristic for which to provide a difference

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between the claims and the cited disclosure then the difference is considered to be so slight as to render the claims obvious. The induction of apoptosis of T-cells is considered to be an inherent trait of the NAP disclosed by Vlasuk. Also the reference teaches that cancer can be treated of which is known to be not subjected to apoptosis but a cancer cell is immortal when left untreated. Therefore, especially since cancer is disclosed to be treatable then T-cell apoptosis is considered to be an inherent property of the NAP (Nematode Extracted Protein). Thus, since cancer can be treated with the NAP, cell death (apoptosis) must be induced by the NAP. However, in the alternative that cell apoptosis induction is not an inherent property then the claims are rendered prima facie obvious over the cited disclosure and the claims would have been expected to be capable of successful T-cell apoptosis as the same is at least suggested, if not taught, by the cited reference. Claims are at least prima facie obvious in the alternative over this newly cited reference.

Claim Rejections - 35 USC § 103

Claims 1 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/12615 and Brophy et al, both cited above, in view of Kalinkovich et al.

The claims are discussed above as are the WO patent and Brophy et al.

Kalinkovich teaches T-cell apoptosis is related to *Necator americanus* infection of mammals, humans specifically. Note page 419, all lines.

The claims differ from the cited disclosures of WO Patent and Brophy et al. in that cell apoptosis is not specifically disclosed. Although it is believed that this is an

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inherent property this rejection is made to supplement the alternative 103 portions of the above rejections.

4. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for the compositions and method of treating inflammation in a human using the compositions as disclosed by WO Patent and Brophy with the expectation that T-cell apoptosis would be induced since Kalinkovich et al. clearly teach that during helminth infection T-cell apoptosis was observed. Therefore, one of skill in the art would have expected successful results for the capability of the compositions to induce T-cell apoptosis as the same as been observed in the cited prior art as evidenced by Kalinkovich. The claims are deemed at least prima facie obvious.

5. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vlasuk et al. in view of Kalinokovich et al., both discussed above.

Claims are discussed above.

Claims differ, if at all, from Vlasuk in that cell apoptosis is not specifically disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was filed to combine the cited disclosures in order to provide for a composition and methods, therefore, with the successful expectation that T-cell apoptosis would be induced by such compositions. Clearly one of skill would have been motivated to provide for these compositions based upon the teachings of the cited prior art. Each of the claimed features are clearly disclosed herein. One of skill would have expected successful results for treating inflammation and cancer in a human being

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using the compositions disclosed by Vlasuk. Cell apoptosis is clearly disclosed by Kalinokovich to be associated and related to *Necator americanus*. Thus, one of skill in the art would have expected that its isolatable products would have the same inherent features as the hookworm from whence it was derived therefrom. Thus, the claims are at

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware
March 20, 2004